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EXHIBIT 27

DECLARATION OF DR. RICHARD B. MOSS, M.D., F.C.C.P.

I, RICHARD B. MOSS, M.D., F.C.C.P., declare as follows:

- 1. My name is Richard B. Moss, M.D., F.C.C.P. I am the chief of the pulmonary division in the Department of Pediatrics and Director of the Stanford Cystic Fibrosis Center at Lucille Packard Children's Hospital at Stanford University Medical Center. I sit on an advisory panel for Chiron Corporation, and I have received research grants from Chiron for clinical studies pertaining to TOBI[®]. My education, training, and experience in the field of medicine, and, particularly, with respect to pulmonology and Cystic Fibrosis are set forth in detail in the true and correct copy of my curriculum vitae, attached as Exhibit A, which I incorporate as if set forth fully herein.
- 2. Cystic fibrosis ("CF") is an autosomal recessive disease that affects approximately 60,000 people worldwide. Mutations in the gene coding for a chloride-channel protein, called the CF transmembrane conductance regulator, result in reduced mucociliary clearance, leaving CF patients especially vulnerable to endobronchial infections, particularly with *Pseudomonas aeruginosa*. Chronic airway infections lead to progressive obstruction of the airways and loss of pulmonary function. According to data provided by the Cystic Fibrosis Foundation, in 2002, more than 85% of CF patient deaths could be attributed to loss of pulmonary function. Relative lung function (expressed as a percentage of the patient's predicted FEV₁ percent predicted) is a significant clinical predictor of mortality in patients with CF. After adjusting for age and gender contributions, the relative risk of death for CF patients doubles with each 10% loss of FEV₁ percent predicted.
- 3. Paeruginosa is the major infectious burden in the airway of CF patients, and this pathogen is present in the lower respiratory tract of nearly 70% of CF patients by the age of 17 years. Acquisition of Paeruginosa is a major event in the natural history of CF lung disease, as its presence is associated with increased rates of lung function decline and is a significant predictor of mortality.
- 4. Chronic respiratory tract infection and a decline in pulmonary function are related to mortality in CF patients. Death rates for CF patients chronically infected with *P aeruginosa* increase slowly with age up to the teenage years, when rates increase more rapidly and then remain fairly constant from the late teens to beyond the age of 30 years. Similarly, mean FEV₁ percent predicted declines rapidly until early adulthood, when the rate of decline levels off. There is an inverse relationship between age and risk of death for any given level of relative lung function. In patients with the same percentage of predicted FEV₁ but an age difference of 10 years, the relative risk of death is doubled for younger patients. Patients who die earlier in life experience significantly higher rates of lung function decline than longer-living patients. In 2002, the median age of death in CF patients in the United States was 24.5 years.
- 5. The central role of *P aeruginosa* in CF lung disease has led to testing of intensive therapy with antipseudomonal antibiotics to suppress infection. Tobramycin is the most frequently prescribed aminoglycoside for the treatment of pulmonary infections in CF patients. Tobramycin is frequently administered IV during periods of acute exacerbations. Because the penetration of tobramycin into sputum is low following IV administration, high doses are

required to achieve concentrations inhibitory to *P aeruginosa*. Moreover, the inactivation of tobramycin in purulent sputum mandates the delivery of 10 to 25 times the minimal inhibitory concentration ("MIC") to achieve bacterial killing. However, high doses of IV tobramycin increase the risk of systemic adverse events ("AEs") such as ototoxicity and nephrotoxicity.

- 6. TOBI®, a nonpyrogenic, preservative-free, pH-adjusted formulation of tobramycin solution for inhalation ("TSI"), administered via a jet nebulizer, allows the delivery of the antibiotic directly to the endobronchial space in the lungs, while minimizing systemic exposure and the associated risk of ototoxicity and nephrotoxicity. Studies have shown significant increases in pulmonary function as well as decreases in hospitalization and IV antibiotic use following long-term, intermittent therapy with tobramycin solution for inhalation. TOBI® earned FDA approval and became commercially available in 1997.
- 7. FDA approval is a complex, often lengthy process that requires clinical studies showing efficacy and safety. Potential new CF therapies require extensive evaluation before they may become approved as a new drug. The process of drug development begins in the laboratory, with years of experiments that test new approaches to treatment, first in vitro (in the test tube), then in living models or systems. If this "preclinical" research is successful, FDA approval is sought to begin clinical trials which involve patients.
- 8. Phase I clinical trials typically last several months and are primarily designed to determine safe doses and administration methods, such as orally, intravenously, or through inhalation. These studies investigate how well the body metabolizes the drug and side effects that may result from increasing the dosage. Drugs that proceed to Phase II trials are tested for efficacy. In most Phase II trials, one group of volunteers may be given the experimental drug while another "control" group will receive a placebo. Safety and effectiveness are examined in these trials. Phase III clinical trials measure how well a drug works in a large number of people. This helps "fine tune" dosage amounts and procedures to ensure a drug's safety and effectiveness. For CF drugs, Phase III clinical trials involve many care centers and hundreds of patients. Once these studies are all successfully completed, the FDA can be asked to approve the therapy for the marketplace. Clinical studies sometimes require Phase IV trials to examine the long-term safety and effectiveness of the drug after licensing or registration.
- 9. As a doctor treating CF in the United States, FDA approval and especially clinical data supporting any treatment for my patients are important. How a drug and device combination will affect the human body is not simple to predict. Clinical studies are necessary to actually test and observe those effects.
- 10. There are some special concerns for obtaining FDA approval for a nebulized drug like TOBI®, which is used chronically in patients that are susceptible to infection. These include:
 - a. Extensive testing of a nebulized drug product with a specific nebulizer (termed a "drug-device combination") in order to characterize the safety and efficacy of that combination. FDA does not allow manufacturers to promote the use of an approved nebulized drug with a different nebulizer without adequate clinical testing because laboratory characterization of a

new nebulizer is inadequate to predict how similarly a new nebulizer will perform relative to a clinically validated nebulizer;

- b. Assurance of sterility of the manufactured product, as CF patients are susceptible to chronic infection with organisms that can contaminate manufacturing facilities, including *Pseudomonas aeruginosa* and *Burkholderia cepacia*; and
- c. Validated in-life testing with appropriate cleaning methods for nebulizers combined with inhaled drugs. Cleaning methods required to assure sterilization of nebulizers can be rigorous, and it is important to validate that nebulizers will continue to deliver appropriate amounts of aerosol for inhalation without causing infection with new organisms in CF patients.
- 11. One unknown factor pertaining to the administration of an unapproved, untested tobramycin solution for inhalation through a device not approved specifically for that drug is the amount of the drug delivered systemically instead of topically. Too much systemic exposure to tobramycin can be toxic.
- 12. Another concern with respect to an unapproved, untested tobramycin solution for inhalation is potential local toxicity and bleeding. The property of the formulation of any tobramycin solution for inhalation needs to be tested for tolerability. CF patients have shown an increased sensitivity to aerosolized antibiotics, resulting in bronchospasms and bleeding.
- 13. Clinical trials are necessary to make sure any tobramycin solution for inhalation delivered through any particular nebulizer is effective in CF patients. Clinical testing is required to determine comparable delivery of the drug into the lungs, change in the microbiology of the airway, and evidence of clinical improvement in lung function.

I declare under penalty of perjury that the foregoing is true and correct. Executed on September 27, 2004.

Richard B. Moss, M.D., F.C.C.P.

Juhra Juhan abaton

CURRICULUM VITAE

Richard Barry Moss, M.D.

PERSONAL INFORMATION

Date of Birth:

October 30, 1949

Place of Birth: Citizenship status: Social Security: New York, NY United States 052-40-1199

Business address:

701A Welch Road, Suite 3328 Palo Alto, CA 94304-5786

Telephone: Telefax: e-mail: Websites: (650) 723-5191 (650) 723-5201 rmoss@stanford.edu

•http://www.lpch.org/clinicalSpecialtiesServices/

COE/PulmonaryCareCF/overview.html

•http://cfcenter.stanford.edu

EDUCATION

Undergraduate:

Columbia University New York, NY

Bachelor of Arts (1971)

Graduate:

State University of New York Downstate Medical Center

New York, NY

Doctor of Medicine (1975)

CLINICAL TRAINING

Internship and Residency:

Pediatrics (1975-77)

Children's Memorial Hospital McGaw Medical Center Northwestern University

Chicago, IL

Fellowships:

Allergy-Immunology (1977-79)

Department of Pediatrics

Stanford University Medical Center

Pediatric Pulmonology (1980-81)

Department of Pediatrics

Stanford University Medical Center

PROFESSIONAL BACKGROUND 1981-1988	Assistant Professor of Pediatrics, Stanford University Medical School
1981-	Attending Physician, Children's Hospital at Stanford/Lucile Packard Children's Hospital at Stanford
1981-	Attending Physician, Stanford University Hospital
1981-1991	Associate Director, Cystic Fibrosis Center Children's Hospital at Stanford Stanford University Medical Center
1982; 1991-1994	Acting Chief, Division of Allergy-Immunology & Respiratory Medicine Department of Pediatrics Stanford University Medical School
1983-2001	Director, Allergy Reference Laboratory Children's Hospital at Stanford, Lucile Packard Children's Hospital at Stanford
1985-	Director, Ross Mosier Laboratory for Cystic Fibrosis Research Children's Hospital at Stanford/ Lucile Packard Children's Hospital at Stanford
1988-1994	Associate Professor of Pediatrics (Clinical), Stanford University School of Medicine
1989-1995	Co-Director, Allergy-Immunology Fellowship Training Program Stanford University School of Medicine
1991-	Director, Stanford Cystic Fibrosis Center
1994-1995	Chief, Division of Allergy-Immunology, & Respiratory Medicine Department of Pediatrics Stanford University Medical School
1994-	Professor of Pediatrics, Stanford University Medical Center
1995-	Chief, Division of Pulmonology Department of Pediatrics Stanford University Medical School

LICENSURE

1976 Illinois, T-7762 1977 California, G035650

BOARD CERTIFICATION

National Board of Medical Examiners
American Board of Pediatrics #6128

American Board of Allergy and Immunology #2206

Diagnostic Laboratory Immunology, a Conjoint Board of

the American Boards of Internal Medicine, Pediatrics,

and Allergy-Immunology #38

HONORS, AWARDS, INVITED LECTURES

1970-1971 Dean's List, Columbia University

1974 Alpha Omega Alpha, National Honor Medical Society

1979 Travel Award, American Academy of Allergy and

Immunology

1980-1981 Medical Research and Training Award, California Thoracic

Society

1980-1981 American Lung Association Training Fellowship

1982 International Travel Award, National Institute of Allergy

and Infectious Disease

1985 International Travel Award, International Association of

Allergology and Clinical Immunology

1986 Invited Speaker, International Symposium on Clinical

Immunology and the Role of IgG4, San Francisco, CA

1987 Invited Symposium Speaker, First North American Cystic

Fibrosis Conference, Toronto, Canada

1990 Invited Plenary Session Speaker, 1990 International Cystic

Fibrosis Conference and Fourth North American Cystic

Fibrosis Conference, Washington, DC

1994-1995 Reviewer, Special Emphasis Panel for Tuberculosis

Academic Awards, National Heart, Lung, and Blood

Institute

1995-1996 Reviewer, Special Emphasis Panel for Asthma Academic

Awards, National Heart, Lung, and Blood Institute

1996-1999 Consultant, The United States Pharmacopoeia Convention 1996 Consultant, Committee to Study Priorities for Vaccine Development, Division of Health Promotion and Disease Prevention, Institute of Medicine, National Academy of Sciences 1996 Reviewer, Special Emphasis Panel, Biological and Physiological Sciences, Division of Research Grants, National Institutes of Health 2003-Reviewer, National Institutes of Health/National Center for Research Resources, General Clinical Research Centers site visit team 2001-present Marquis' Who's Who in Medicine and Healthcare Consumers' Research Council of America, America's Best Pediatricians – Pulmonology Best Doctors, Inc., Best Doctors in America 2003 CFRI Professional Excellence Award

PROFESSIONAL SOCIETIES

Fellow of the American Academy of Allergy, Asthma, and Immunology Fellow of the American Academy of Pediatrics Fellow of the American College of Chest Physicians American Thoracic Society

GRANTS - completed

1983-1984

National Institutes of Health Biomedical Research Support
Grants, "Blocking Antibodies to Pseudomonas aeruginosa
in Cystic Fibrosis" (P.I.)

Miles Pharmaceuticals, Inc., "Multicenter Collaborative
Project: Pseudomonas aeruginosa Endobronchial Infection
in Cystic Fibrosis. A Prospective Double-blind Controlled
Study of Two Antimicrobial Regimens," (D82-033) (CoInvestigator)

MAST Immunosystems, Inc., "A Comparison of the
MAST Inhalant Profile and the Phadezyme RAST" (P.I.)

Cystic Fibrosis Foundation Research Grant G104 6-01,

"Natural and Human Hybridoma CF Antipseudomonal

Antibodies" (P.I.)

1985-1986

1986-1987	Beecham Pharmaceuticals, Inc., "A Multicenter Observerblind Study of Antibiotic Therapy of <i>Pseudomonas aeruginosa</i> Bronchopulmonary Infection in Cystic Fibrosis: Comparison of Three Antimicrobial Drug Regimens," (TIM19-0) (Co-Investigator)
1986-1987	Glaxo Pharmaceuticals, Inc., "Extended Home Intravenous Therapy in Cystic Fibrosis Patients," (CAZ-503) (Co-Investigator)
1986-1990	National Heart, Lung, and Blood Institute, "Late Sequelae of Bronchopulmonary Dysplasia" (RO1 HL36796) (Co-P.I. with Bill Northway)
1987	3M Diagnostic Systems, Inc., "Comparison of Phadezyme RAST to 3M Diagnostic Systems FAST for Specific IgE" (P.I.)
1987-1989	E.R. Squibb & Sons, Inc., "Evaluation of the Immunologic Cross-Reactivity of Aztreonam Therapy in Cystic Fibrosis Patients Allergic to Penicillin and/or Cephalosporin Antibiotics" (18554-145) (Stanford P.I.)
1990-1991	Cystic Fibrosis Research, Inc., "Mechanism of β -Lactam Drug Allergy in Cystic Fibrosis" (P.I.)
1991-1992	Stanford Office of Technology Research Incentive Fund, "Evaluation of Maxillary Sinus Treatments in Patients with Antrostomies" (Co-Investigator)
1991-1993	Genentech, Inc., "A Phase III, Multicenter, Double-blind, Placebo-controlled, Parallel Study to Evaluate the Safety and Efficacy of Aerosolized Recombinant Human DNase I in Patients with Cystic Fibrosis" (z0343g) (Stanford P.I.)
1992-1993	Genentech, Inc., "A Phase II, Multicenter, Double-blind, Placebo-controlled, Parallel Study to Evaluate the Safety and Efficacy of Aerosolized Recombinant Human DNase I in Hospitalized Patients with Cystic Fibrosis Experiencing Acute Pulmonary Exacerbations" (20401g) (Stanford P.I.)
1992-1993	Genentech, Inc., "A Multicenter Open-label Treatment Protocol to Provide Aerosolized rhDNase Therapy to Patients with Cystic Fibrosis" (z0507g-A2) (Stanford P.I.)

1992-1994	Genentech, Inc., "A Multicenter Epidemiologic Protocol to Evaluate Pulmonary Function and the Rate of Respiratory Tract Infections in Patients with Cystic Fibrosis" (z0525n) (Stanford P.I.)
1992-1993	Cystic Fibrosis Foundation, "Cystic Fibrosis Trans- membrane Conductance Regulator Expression in Human T Cell Clones" (Co-Investigator)
1993	Genentech, Inc., "A Randomized Multicenter Study to Evaluate the Safety and Efficacy of Aerosolized Recombinant Human DNase I administered with Three Different Nebulizers in Patients with Cystic Fibrosis" (z0555g) (Stanford P.I.)
1993	Genentech, Inc., "A Multicenter, Double-blind, Placebo- controlled Protocol to Evaluate the Safety and Efficacy of Aerosolized Recombinant human DNase I Therapy in Patients with Cystic Fibrosis Who Have Advanced Lung Disease" (z0554g) (Stanford P.I.)
1993-1994	Cystic Fibrosis Foundation, "CFTR, Chloride Conductance, and Immunocompetence in T Cells" (Co-Investigator)
1993-1994	Genentech, Inc., "Effect of Device Resistance and Dynamic Lung Function on Peak Inspiratory Flow Rates in Chronic Obstructive Lung Diseases" (z0596n) (Co-investigator)
1993-1994	Univax Biologics, Inc., "A Single-blind, Multi-Center, Study to Evaluate the Safety and Pharmacokinetics of a Hyperimmune Immunoglobulin Intravenous Targeted Against Mucoid <i>Pseudomonas aeruginosa</i> in Patients with Cystic Fibrosis" (UNX-0401) (P.I.)
1992-1995	National Institute of Diabetes and Digestive and Kidney Diseases RO1 DK 45910-01, "Ursodeoxycholic Acid Therapy in Patients with Cystic Fibrosis-Associated Liver Disease" (Stanford Co-P.I. with Ricardo Castillo)
1994-1995	PathoGenesis, Inc., "A Phase II Clinical Trial to Compare Safety, Efficacy and Pharmacokinetics of an Aminoglycoside (Tobramycin) Formulation Administered by 3 Different Nebulizer Delivery Systems to Patients with Cystic Fibrosis" (PC-TNDS-001) (Stanford P.I.)

1994-1996	Genentech, Inc., "A Phase IV, Multicenter Study to Monitor the Long-term Safety and Efficacy of Pulmozyme in Cystic Fibrosis Patients Who Participated in a Phase III Trial" (z0620n) (Stanford P.I.)
1995-1996	PathoGenesis, Inc., "A Phase III Placebo Controlled Trial to Study the Safety and Efficacy of Tobramycin for Inhalation in Patients with Cystic Fibrosis" (PC-TNDS-002) (Stanford P.I.)
1994-1995	Smith Kline Beecham, Inc., "A Multicenter, Double-Blind, Placebo-Controllled, Parallel-Group Comparison of the Safety and Efficacy of Oral Twice-Daily Administration of SB205312 with Inhaled Vanceril in Patients with Mild to Moderate Asthma" (205312/011) (Stanford P.I.)
1995-1996	Univax Biologicals, Inc./North American Biologicals, Inc., "A Randomized, Multi-Center, Double-Blind, Placebo Exopolysaccharide <i>Pseudomonas aeruginosa</i> Immune Globulin Intravenous (Human) (MEP IGIV) in Reducing the Frequency of Acute Pulmonary Exacerbation in Patients with Cystic Fibrosis" (UNX-0402) (Stanford P.I.)
1995-1996	Cystic Fibrosis Foundation, "Assessment of Safety and Efficacy of Nebulizers" (Stanford P.I.)
1995-1996	NCRR General Clinical Research Center M01 RR00070/ Cystic Fibrosis Research, Inc./Targeted Genetics, Inc., "Phase I Evaluation of Adeno-Associated Virus Mediated Gene Transfer of the Cystic Fibrosis Transmembrane Conductance Regulator in the Maxillary Sinus of Patients with Antrostomies" (Co-Investigator)
1996-1997	Cystic Fibrosis Research, Inc., "T Cells in Cystic Fibrosis: Interleukin 10 Deficiency" (P.I.)
1996-1997	Immuno Clinical Research Corp., "A Revised Open-label Study of C1-Inhibitor (Human) Vapor Treated Immuno as a Therapeutic Agent for Acute Attacks of Hereditary Angioedema (ICRC-091) (Stanford P.I.)
1996-1997	Medical Graphics, Inc., "Electron Beam Computed Tomography of the Chest in Patients with Cystic Fibrosis" (co-P.I. with Terry Robinson)
1996-199 8	PathoGenesis, Inc., "An Open-Label Follow-On Trial of Tobramycin Solution for Inhalation in Patients with CF" (PC-TNDS-004) (Stanford P.I.)

SciClone Pharmaceuticals, Inc., "A Phase I Trial of CPX in Adult Patients with Mild Cystic Fibrosis" (CPX-CLP-PCO-11/19/96-00) (Stanford P.I.) 1996-1998 NCRR General Clinical Research Center M01 RR00070/ Cystic Fibrosis Research, Inc./Targeted Genetics, Inc., "Phase II Evaluation of Adeno-Associated Virus Mediated Gene Transfer of the Cystic Fibrosis Transmembrane Conductance Regulator in the Maxillary Sinus of Patients with Antrostomies" (Co-Investigator) 1996-1998 Cystic Fibrosis Research, Inc., "Electron Beam Computed Tomography, Pulmonary Function, and Exercise Endurance During a Pulmonary Exacerbation in Patients with Cystic Fibrosis" (P.I.) 1996-1998 The DuPont Merck Pharmaceutical Company, "A Phase IIA Dose-Escalation Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Multiple Doses of DMP 777 in Adult Patients 18 Years of Age and Older with Cystic Fibrosis" (DMP 777-003) (Stanford P.I.) 1997-1999 The DuPont Merck Pharmaceutical Company "A Phase IIA Multiple Dose-Escalation Study to Evaluate the Lung-Specific Bioefficacy of Three Different Dose Levels of DMP 777 in Adult Patients 18 Years of Age and Older with Cystic Fibrosis" (DMP 777-004) (Stanford P.I.) 1997-1999 Cystic Fibrosis Foundation, "High Resolution CT Imaging in Mild Cystic Fibrosis Pulmonary Disease Using Electron Beam Computed Tomography" (P.I.) 1998-2000 Genentech, Inc., "A Multicenter, International, Randomized, Placebo-controlled, Double-blind Study to Determine the Effect of Pulmozyme® on Pulmonary Function Over 96 Weeks in Subjects with Cystic Fibrosis Aged 6-10 Years" (20712) (Stanford P.I.) 1998-2000 NCRR General Clinical Research Center M01 RR00070/ Targeted Genetics, Inc., "A Phase I Study of Aerosolized tgAAVCF for the Treatment of Cystic Fibrosis Patients with Mild Lung Disease" (Stanford P.I.)		
Cystic Fibrosis Research, Inc./Targeted Genetics, Inc., "Phase II Evaluation of Adeno-Associated Virus Mediated Gene Transfer of the Cystic Fibrosis Transmembrane Conductance Regulator in the Maxillary Sinus of Patients with Antrostomies" (Co-Investigator) 1996-1998 Cystic Fibrosis Research, Inc., "Electron Beam Computed Tomography, Pulmonary Function, and Exercise Endurance During a Pulmonary Exacerbation in Patients with Cystic Fibrosis" (P.I.) 1996-1998 The DuPont Merck Pharmaceutical Company, "A Phase IIA Dose-Escalation Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Multiple Doses of DMP 777 in Adult Patients 18 Years of Age and Older with Cystic Fibrosis" (DMP 777-003) (Stanford P.I.) 1997-1999 The DuPont Merck Pharmaceutical Company "A Phase IIA Multiple Dose-Escalation Study to Evaluate the Lung- Specific Bioefficacy of Three Different Dose Levels of DMP 777 in Adult Patients 18 Years of Age and Older with Cystic Fibrosis" (DMP 777-004) (Stanford P.I.) 1997-1999 Cystic Fibrosis Foundation, "High Resolution CT Imaging in Mild Cystic Fibrosis Pulmonary Disease Using Electron Beam Computed Tomography" (P.I.) 1998-2000 Genentech, Inc., "A Multicenter, International, Randomized, Placebo-controlled, Double-blind Study to Determine the Effect of Pulmozyme® on Pulmonary Function Over 96 Weeks in Subjects with Cystic Fibrosis Aged 6-10 Years" (20713g) (Stanford P.I.) 1998-2000 NCRR General Clinical Research Center M01 RR00070/ Targeted Genetics, Inc., "A Phase I Study of Aerosolized tgAAVCF for the Treatment of Cystic Fibrosis Patients with Mild Lung Disease" (Stanford P.I.)	1996-1998	Adult Patients with Mild Cystic Fibrosis" (CPX-
Tomography, Pulmonary Function, and Exercise Endurance During a Pulmonary Exacerbation in Patients with Cystic Fibrosis" (P.I.) The DuPont Merck Pharmaceutical Company, "A Phase IIA Dose-Escalation Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Multiple Doses of DMP 777 in Adult Patients 18 Years of Age and Older with Cystic Fibrosis" (DMP 777-003) (Stanford P.I.) The DuPont Merck Pharmaceutical Company "A Phase IIA Multiple Dose-Escalation Study to Evaluate the Lung- Specific Bioefficacy of Three Different Dose Levels of DMP 777 in Adult Patients 18 Years of Age and Older with Cystic Fibrosis" (DMP 777-004) (Stanford P.I.) 1997-1999 Cystic Fibrosis Foundation, "High Resolution CT Imaging in Mild Cystic Fibrosis Pulmonary Disease Using Electron Beam Computed Tomography" (P.I.) 1998-2000 Genentech, Inc., "A Multicenter, International, Randomized, Placebo-controlled, Double-blind Study to Determine the Effect of Pulmozyme® on Pulmonary Function Over 96 Weeks in Subjects with Cystic Fibrosis Aged 6-10 Years" (20713g) (Stanford P.I.) NCRR General Clinical Research Center M01 RR00070/ Targeted Genetics, Inc., "A Phase I Study of Aerosolized tgAAVCF for the Treatment of Cystic Fibrosis Patients with Mild Lung Disease" (Stanford P.I.)	1996-1998	Cystic Fibrosis Research, Inc./Targeted Genetics, Inc., "Phase II Evaluation of Adeno-Associated Virus Mediated Gene Transfer of the Cystic Fibrosis Transmembrane Conductance Regulator in the Maxillary Sinus of Patients
IIA Dose-Escalation Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Multiple Doses of DMP 777 in Adult Patients 18 Years of Age and Older with Cystic Fibrosis" (DMP 777-003) (Stanford P.I.) 1997-1999 The DuPont Merck Pharmaceutical Company "A Phase IIA Multiple Dose-Escalation Study to Evaluate the Lung- Specific Bioefficacy of Three Different Dose Levels of DMP 777 in Adult Patients 18 Years of Age and Older with Cystic Fibrosis" (DMP 777-004) (Stanford P.I.) 1997-1999 Cystic Fibrosis Foundation, "High Resolution CT Imaging in Mild Cystic Fibrosis Pulmonary Disease Using Electron Beam Computed Tomography" (P.I.) 1998-2000 Genentech, Inc., "A Multicenter, International, Randomized, Placebo-controlled, Double-blind Study to Determine the Effect of Pulmozyme® on Pulmonary Function Over 96 Weeks in Subjects with Cystic Fibrosis Aged 6-10 Years" (20713g) (Stanford P.I.) NCRR General Clinical Research Center M01 RR00070/ Targeted Genetics, Inc., "A Phase I Study of Aerosolized tgAAVCF for the Treatment of Cystic Fibrosis Patients with Mild Lung Disease" (Stanford P.I.) 1998 Genentech, Inc., "Validation of a Disease-specific Quality	1996-1998	Tomography, Pulmonary Function, and Exercise Endurance During a Pulmonary Exacerbation in Patients
IIA Multiple Dose-Escalation Study to Evaluate the Lung- Specific Bioefficacy of Three Different Dose Levels of DMP 777 in Adult Patients 18 Years of Age and Older with Cystic Fibrosis" (DMP 777-004) (Stanford P.I.) 1997-1999 Cystic Fibrosis Foundation, "High Resolution CT Imaging in Mild Cystic Fibrosis Pulmonary Disease Using Electron Beam Computed Tomography" (P.I.) 1998-2000 Genentech, Inc., "A Multicenter, International, Randomized, Placebo-controlled, Double-blind Study to Determine the Effect of Pulmozyme® on Pulmonary Function Over 96 Weeks in Subjects with Cystic Fibrosis Aged 6-10 Years" (20713g) (Stanford P.I.) 1998-2000 NCRR General Clinical Research Center M01 RR00070/ Targeted Genetics, Inc., "A Phase I Study of Aerosolized tgAAVCF for the Treatment of Cystic Fibrosis Patients with Mild Lung Disease" (Stanford P.I.) 1998 Genentech, Inc., "Validation of a Disease-specific Quality	1996-1998	IIA Dose-Escalation Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Multiple Doses of DMP 777 in Adult Patients 18 Years of Age and Older with Cystic Fibrosis" (DMP 777-003)
in Mild Cystic Fibrosis Pulmonary Disease Using Electron Beam Computed Tomography" (P.I.) 1998-2000 Genentech, Inc., "A Multicenter, International, Randomized, Placebo-controlled, Double-blind Study to Determine the Effect of Pulmozyme® on Pulmonary Function Over 96 Weeks in Subjects with Cystic Fibrosis Aged 6-10 Years" (z0713g) (Stanford P.I.) NCRR General Clinical Research Center M01 RR00070/ Targeted Genetics, Inc., "A Phase I Study of Aerosolized tgAAVCF for the Treatment of Cystic Fibrosis Patients with Mild Lung Disease" (Stanford P.I.) 1998 Genentech, Inc., "Validation of a Disease-specific Quality	1997-1999	IIA Multiple Dose-Escalation Study to Evaluate the Lung- Specific Bioefficacy of Three Different Dose Levels of DMP 777 in Adult Patients 18 Years of Age and Older
Randomized, Placebo-controlled, Double-blind Study to Determine the Effect of Pulmozyme® on Pulmonary Function Over 96 Weeks in Subjects with Cystic Fibrosis Aged 6-10 Years" (z0713g) (Stanford P.I.) NCRR General Clinical Research Center M01 RR00070/ Targeted Genetics, Inc., "A Phase I Study of Aerosolized tgAAVCF for the Treatment of Cystic Fibrosis Patients with Mild Lung Disease" (Stanford P.I.) Genentech, Inc., "Validation of a Disease-specific Quality	1997-1999	in Mild Cystic Fibrosis Pulmonary Disease Using Electron
Targeted Genetics, Inc., "A Phase I Study of Aerosolized tgAAVCF for the Treatment of Cystic Fibrosis Patients with Mild Lung Disease" (Stanford P.I.) Genentech, Inc., "Validation of a Disease-specific Quality	1998-2000	Randomized, Placebo-controlled, Double-blind Study to Determine the Effect of Pulmozyme® on Pulmonary Function Over 96 Weeks in Subjects with Cystic Fibrosis
	1998-2000	Targeted Genetics, Inc., "A Phase I Study of Aerosolized tgAAVCF for the Treatment of Cystic Fibrosis Patients
	1998	

1999-2000	IntraBiotics Pharmaceuticals, Inc., "A Phase I, Randomized, Placebo-controlled, Double-blind, Multicenter Safety and Tolerability Study of Ascending Multiple Inhaled Doses of IB-367 in Adult Patients with Cystic Fibrosis" (Stanford P.I.)
1999-2001	Cystic Fibrosis Foundation, "Diabetes Therapy to Ameliorate Protein Catabolism in CF" (Stanford P.I.)
1999-2001	Cystic Fibrosis Foundation Therapeutics, Inc., and Chiron Corp., "A Phase II Multicenter Randomized Trial of Tobramycin for Inhalation in Young Children with Cystic Fibrosis" (IT003) (Stanford P.I.)
2000-2001	Medimmune Inc., "A Phase IV Study of the Safety of Synagis® (Palivizumab) for Prophylaxis of Respiratory Syncytial Virus in Children with Cystic Fibrosis" (Stanford P.I.)
1997-2000	Ross Mosier Fund, "Cystic Fibrosis Alleles" (Co-P.I. with Jeff Wine)
1997-1999	Cystic Fibrosis Foundation Therapeutics, Inc., "Spirometer-Gated HRCT as an Outcome Measure in Mild CF." (P.I.).
1998-2000	Genentech, Inc., "Pulmozyme in CF Patients Using Spirometer Computerized Tomography" (z1970n) (P.I.)
1998-2003	Cystic Fibrosis Foundation, "Comparison of Single-Dose Aminoglycoside versus Conventional Therapy Combined with Beta-Lactam in Cystic Fibrosis Patients with Pulmonary Exacerbations" (Stanford P.I.)
1999-2001	AstraZeneca, Inc., "Safety and Efficacy Study of Two Dosage Levels of Pulmicort Respules vs Placebo in Infants 6 to 12 Months with Mild-Moderate Asthma" (SD-004-0732) (Stanford P.I.)
2000-2002	Cystic Fibrosis Foundation Therapeutics, Inc., and Intermune, Inc., "A Phase I/II Study of Interferon Gamma-1b by Inhalation for the Treatment of Patients with Cystic Fibrosis" (GICF-001) (National P.I.)
2001-2003	Cystic Fibrosis Foundation Therapeutics, Inc., and Targeted Genetics, Inc., "A Multicenter, Double-Blind,

P.I.) Cystic Fibrosis Foundation Therapeutics, Inc., "Validation of Sputum Induction as Outcome Measure for Lower Airway Sampling in Patients with Cystic Fibrosis" (Stanford P.I.) 2001-2002 Cystic Fibrosis Foundation Therapeutics, Inc. and Boehringer Ingelheim, "A Randomized, Double-blind Within Dose, Placebo-controlled study to investigate the Safety, Tolerability and Pharmacokinetics of Increasing Oral Doses of BIIL 284 BS in Adult and Pediatric Cystic Fibrosis Patients" (BI 543.36) (Stanford P.I.) 2001-2002 Cystic Fibrosis Foundation Therapeutics, Inc., and Boehringer Ingelheim, "A randomized, double-blind within dose, placebo-controlled study to investigate the safety, tolerability and pharmacokinetics of repeated oral doses (15-day dosing) of BIIL 284 BS in adult (300 mg) and pediatric (150 mg) cystic fibrosis patients" (BI 543.37) (Stanford P.I.) 2001-2003 Cystic Fibrosis Foundation Therapeutics, Inc., "Standardization of Cystic Fibrosis Sweat Rate Procedure' (Stanford P.I.) 2001-2003 Cystic Fibrosis Foundation Therapeutics, Inc., "Cystic Fibrosis Twin Study" (Stanford P.I.) 2002-2003 Cystic Fibrosis Foundation Therapeutics, Inc., and Altus Biologics, Inc., "A Phase I, Open-Label Safety and Tolerability Study of Oral TheraCLEC-Total in Subjects with Cystic Fibrosis (Stanford P.I.) Cystic Fibrosis Foundation Therapeutics, Inc., and Boehringer Ingelheim, Inc, "A randomized, double-blind, placebo-controlled study to investigate the efficacy and		
"Standardization of the Measurement of the Nasal Membrane Transepithelial-Potential Difference" (Stanford P.I.) 2001-2002 Cystic Fibrosis Foundation Therapeutics, Inc., "Validation of Sputum Induction as Outcome Measure for Lower Airway Sampling in Patients with Cystic Fibrosis" (Stanford P.I.) 2001-2002 Cystic Fibrosis Foundation Therapeutics, Inc. and Boehringer Ingelheim, "A Randomized, Double-blind Within Dose, Placebo-controlled study to investigate the Safety, Tolerability and Pharmacokinetics of Increasing Oral Doses of BIIL 284 BS in Adult and Pediatric Cystic Fibrosis Patients" (BI 543.36) (Stanford P.I.) 2001-2002 Cystic Fibrosis Foundation Therapeutics, Inc., and Boehringer Ingelheim, "A randomized, double-blind within dose, placebo-controlled study to investigate the safety, tolerability and pharmacokinetics of repeated oral doses (15-day dosing) of BIIL 284 BS in adult (300 mg) and pediatric (150 mg) cystic fibrosis patients" (BI 543.37) (Stanford P.I.) 2001-2003 Cystic Fibrosis Foundation Therapeutics, Inc., "Standardization of Cystic Fibrosis Sweat Rate Procedure" (Stanford P.I.) 2001-2003 Cystic Fibrosis Foundation Therapeutics, Inc., and Altus Biologics, Inc., "A Phase I, Open-Label Safety and Tolerability Study of Oral TheraCLEC-Total in Subjects with Cystic Fibrosis Foundation Therapeutics, Inc., and Boehringer Ingelheim, Inc, "A randomized, double-blind, placebo-controlled study to investigate the efficacy and		tgAAVCF in Cystic Fibrosis Patients with Mild Lung
of Sputum Induction as Outcome Measure for Lower Airway Sampling in Patients with Cystic Fibrosis" (Stanford P.I.) 2001-2002 Cystic Fibrosis Foundation Therapeutics, Inc. and Boehringer Ingelheim, "A Randomized, Double-blind Within Dose, Placebo-controlled study to investigate the Safety, Tolerability and Pharmacokinetics of Increasing Oral Doses of BIIL 284 BS in Adult and Pediatric Cystic Fibrosis Patients" (BI 543.36) (Stanford P.I.) 2001-2002 Cystic Fibrosis Foundation Therapeutics, Inc., and Boehringer Ingelheim, "A randomized, double-blind with dose, placebo-controlled study to investigate the safety, tolerability and pharmacokinetics of repeated oral doses (15-day dosing) of BIIL 284 BS in adult (300 mg) and pediatric (150 mg) cystic fibrosis patients" (BI 543.37) (Stanford P.I.) 2001-2003 Cystic Fibrosis Foundation Therapeutics, Inc., "Standardization of Cystic Fibrosis Sweat Rate Procedure' (Stanford P.I.) 2001-2003 Cystic Fibrosis Foundation Therapeutics, Inc., "Cystic Fibrosis Twin Study" (Stanford P.I.) 2002-2003 Cystic Fibrosis Foundation Therapeutics, Inc., and Altus Biologics, Inc., "A Phase I, Open-Label Safety and Tolerability Study of Oral TheraCLEC-Total in Subjects with Cystic Fibrosis Foundation Therapeutics, Inc., and Boehringer Ingelheim, Inc, "A randomized, double-blind, placebo-controlled study to investigate the efficacy and	2001-2002	"Standardization of the Measurement of the Nasal Membrane Transepithelial-Potential Difference" (Stanford
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Boehringer Ingelheim, "A randomized, double-blind within dose, placebo-controlled study to investigate the safety, tolerability and pharmacokinetics of repeated oral doses (15-day dosing) of BIIL 284 BS in adult (300 mg) and pediatric (150 mg) cystic fibrosis patients" (BI 543.37) (Stanford P.I.) 2001-2003 Cystic Fibrosis Foundation Therapeutics, Inc., "Standardization of Cystic Fibrosis Sweat Rate Procedure" (Stanford P.I.) 2001-2003 Cystic Fibrosis Foundation Therapeutics, Inc., "Cystic Fibrosis Twin Study" (Stanford P.I.) 2002-2003 Cystic Fibrosis Foundation Therapeutics, Inc., and Altus Biologics, Inc., "A Phase I, Open-Label Safety and Tolerability Study of Oral TheraCLEC-Total in Subjects with Cystic Fibrosis (Stanford P.I.) 2003-2004 Cystic Fibrosis Foundation Therapeutics, Inc., and Boehringer Ingelheim, Inc, "A randomized, double-blind, placebo-controlled study to investigate the efficacy and	2001-2002	Boehringer Ingelheim, "A Randomized, Double-blind Within Dose, Placebo-controlled study to investigate the Safety, Tolerability and Pharmacokinetics of Increasing Oral Doses of BIIL 284 BS in Adult and Pediatric Cystic
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Fibrosis Twin Study" (Stanford P.I.) 2002-2003 Cystic Fibrosis Foundation Therapeutics, Inc., and Altus Biologics, Inc., "A Phase I, Open-Label Safety and Tolerability Study of Oral TheraCLEC-Total in Subjects with Cystic Fibrosis (Stanford P.I.) 2003-2004 Cystic Fibrosis Foundation Therapeutics, Inc., and Boehringer Ingelheim, Inc, "A randomized, double-blind, placebo-controlled study to investigate the efficacy and	2001-2003	"Standardization of Cystic Fibrosis Sweat Rate Procedure"
Biologics, Inc., "A Phase I, Open-Label Safety and Tolerability Study of Oral TheraCLEC-Total in Subjects with Cystic Fibrosis (Stanford P.I.) 2003-2004 Cystic Fibrosis Foundation Therapeutics, Inc., and Boehringer Ingelheim, Inc, "A randomized, double-blind, placebo-controlled study to investigate the efficacy and	2001-2003	• • • • • • • • • • • • • • • • • • • •
Boehringer Ingelheim, Inc, "A randomized, double-blind, placebo-controlled study to investigate the efficacy and	2002-2003	Biologics, Inc., "A Phase I, Open-Label Safety and Tolerability Study of Oral TheraCLEC-Total in Subjects
	2003-2004	Boehringer Ingelheim, Inc, "A randomized, double-blind, placebo-controlled study to investigate the efficacy and safety of 24 weeks of oral treatment with BIIL 284 BS in adult (75 mg, 150 mg) and pediatric (75 mg) cystic fibrosis

2003-2004	Cystic Fibrosis Foundation Therapeutics, Inc., and Inspire Pharmaceuticals, Inc., "A Multi-Center, Double-Blind, Randomized, Placebo-Controlled, 28-Day Study of INS37217 Inhalation Solution in Subjects with Mild to Moderate Cystic Fibrosis Lung Disease" (Co-investigator)
2003-2004	Chiron, "A Phase I Single-dose, Dose-escalation Trial Comparing Safety, Pharmokinetics and Delivery Time of Tobramycin Dry Powder for Inhalation Administered by Nektar T-326 Dry Powder Inhaler Device to Tobramycin Solution for Inhalation Administered by a Pari LC Plus Jet Nebulizer/DeVilbiss PulmoAide Compressor in Cystic Fibrosis Patients (Co-investigator)
2003-2004	Cystic Fibrosis Foundation Therapeutics, Inc., and Corus Pharma, "A Blinded, Multicenter, Randomized, Placebo-Controlled Trial with Aztreonam for Inhalation in Cystic Fibrosis Patients with Lung Disease Due to P. aeruginosa Infection" (Co-investigator)
2003-2004	Cystic Fibrosis Foundation Therapeutics, Inc., and Altus Biologicals, Inc., "A Phase 2, Active Run-in Randomized, Double Blind Dose Ranging Study of Oral TheraCLEC-Total in Cystic Fibrosis Subjects with Exocrine Pancreatic Insufficiency" (P.I.)
<u>ACTIVE GRANTS 2004:</u> 1991-	Cystic Fibrosis Foundation, "Stanford Cystic Fibrosis Center" (Center Director)
1994-	Genentech, Inc., "Epidemiologic Study of Cystic Fibrosis" (z0595) (Stanford P.I.)
1999-	Cystic Fibrosis Foundation Therapeutics, Inc., "Therapeutics Development Network Center" (P.I.)
2001-	NIH-NIDDK, "Diabetes Therapy to Improve Muscle Mass and Clinical Status in CF Subjects with Abnormal Glucose Tolerance" (Stanford co-P.I. with Noreen Henig)
2001-	NIH-NIDDK, Cystic Fibrosis Foundation Therapeutics, Inc., and Chiron Corp., "An Open Label Study of Tobramycin for Inhalation in Young Children with Cystic Fibrosis" (IT004) (Stanford P.I.)
2001-	Cystic Fibrosis Foundation Therapeutics, Inc., "Evaluation of Pulmonary Function Tests from Raised Lung Volumes

	as Outcome Measures for Clinical Trials in Infants with Cystic Fibrosis" (Stanford P.I.)		
2001-	NIH-NHLBI, "Genetic Modifiers in Cystic Fibrosis Lung Disease" (Co-investigator)		
2003-	Thrasher Foundation, "Improving Health Care Outcomes of Children and Adolescents with Chronic Disease" (Co-PI with David Bergman MD)		
2003-	Cystic Fibrosis Foundation Therapeutics, Inc., and Targeted Genetics, Inc., "A Multicenter, Double-blind, Placebo-Controlled Phase II Study of Aerosolized tgAAVCF for the Treatment of Cystic Fibrosis" (25 E01) (National P.I.)		
2003-	Cystic Fibrosis Foundation, "A Study of the Effects of Glutathione and N-Acetylcysteine on Lung Inflammation in Cystic Fibrosis Patients" (Co-investigator)		
2004-	Cystic Fibrosis Foundation Therapeutics, Inc., "Assessment of induced sputum as a tool to evaluate anti-inflammatory agents in pateints with cystic fibrosis (Stanford P.I.)		
UNIVERSITY AND HOSPITAL COMMITTEES Chair, Pharmacy and Therapeutics Committee Children's Hospital at Stanford 1982-1991			
Evaluation and Planning Committee	ē.		
Department of Pediatrics Stanford University School of Medicine 1982-1983			
Committee on Research, Department of Pediatrics Stanford University School of Medicine 1984-1985			
Chair, Pharmacy Task Force			
Academic Program Committee Lucile Salter Packard Children's Ho	ospital 1985-1986		
Quality Assurance Committee Children's Hospital at Stanford Respiratory Therapy Task Force,	1985-1991		
Academic Program Committee Lucile Salter Packard Children's Ho	ospital 1985-1986		

Committee on the Pediatric Residency, Department of Pediatrics Stanford University School of Medicine	1986-1987
Chair, Task Force on Postoperative Care Children's Hospital at Stanford	1988
Search Committee, Chief Operating Officer Lucile Salter Packard Children's Hospital	1989
Quality Improvement Committee Lucile Salter Packard Children's Hospital	1991-1993
Nutrition and Total Parenteral Nutrition Committee Lucile Salter Packard Children's Hospital	1991-1998
Infection Control Committee Lucile Salter Packard Children's Hospital	1992-
Home Health Care Committee Lucile Salter Packard Children's Hospital	1992-1997
Physician Hospital Organization Utilization Management/Quality Assurance Committee Lucile Salter Packard Children's Hospital	1994-1996
Dean's Task Force on Gene Therapy Stanford University School of Medicine	1994
Genetics Chief Search Committee Department of Pediatrics Stanford University School of Medicine	1994
Chair, Pulmonary Division Chief Search Committee Department of Pediatrics Stanford University School of Medicine	1995-1996
Documentation & Compliance Committee Lucile Salter Packard Children's Hospital	1998-
Ambulatory Services & Space Task Force Lucile Salter Packard Children's Hospital	1998-2000
Asthma, Pulmonary and TB Planning Group Children's Health Initiative UCSF Stanford Health Care	1999

GCRC Oversight & Review Committee NCCR General Clinical Research Center Stanford University Medical Center

1999-

Clinical Operations & Budget Committee Lucile Packard Children's Hospital

2000-

Faculty Practice Organization Management Committee

2004-

Lucile Packard Children's Hospital

EXTRAMURAL PROFESSIONAL COMMITTEES & ACTIVITIES

Ad Hoc Grant Reviewer

March of Dimes 1985

External Advisory Board

NIH Cystic Fibrosis Research Center

Case Western Reserve Medical School 1985-1991

Ad Hoc Grant Reviewer

Canadian Cystic Fibrosis Foundation 1986, 1997

Clinical Research Grant Review Committee

Cystic Fibrosis Foundation 1987-

Section Abstract Reviewer

North American Cystic Fibrosis Conference 1988-1992, 1995-1998, 2004

Site Visit Review Board

Cystic Fibrosis Foundation 1988

Chairman, GAP Conference on Infection, Immunity

and Inflammation

Cystic Fibrosis Foundation 1988

Scientific Advisory Panel on Allergy and Immunology

California Medical Association 1990-1995

Ad Hoc Grant Reviewer

Cystic Fibrosis Research, Inc. 1991-

Immunotherapy Advisory Board

Cystic Fibrosis Foundation & Univax Biologicals, Inc. 1992-1994

Chair, Data Safety Monitoring Committee

National Multicenter Controlled Pentoxifylline Trial

in Patients with Cystic Fibrosis

Hoechst-Roussel Pharmaceuticals, Inc. 1993-1995

Special Emphasis Panel on Asthma Academic Awards National Heart, Blood and Lung Institute	1994-1995
Special Emphasis Panel on Tuberculosis Academic Award National Heart, Blood and Lung Institute	s 1994-1995
Data Safety Monitoring Committee Multicenter Controlled Exosurf Trial in Patients with Cystic Fibrosis Burroughs-Wellcome, Inc.	1995
North American Conference Planning Committee Cystic Fibrosis Foundation	1995-1998, 2004
Clinical Practice Guidelines Committee Cystic Fibrosis Foundation	1995-1996
Merrem® Advisory Board Zeneca Pharmaceuticals, Inc.	1995-1996
Ad Hoc Grant Reviewer National Science Foundation of Switzerland	1995, 1999
Committee to Study Priorities for Vaccine Development Institute of Medicine National Academy of Sciences	1996
Ad Hoc Grant Reviewer Cystic Fibrosis Association of Germany	1996
Ad Hoc Grant Reviewer Canadian Cystic Fibrosis Foundation Scientific Advisory Board, AeroGen Corporation	1997-
Tobi [®] Advisory Board Chiron Corporation	1999-
Steering Committee CFF Therapeutics Development Center Network	1999-
The Chest Foundation American College of Chest Physicians Clinical Research Trainee Awards Committee	2001-
California Medical Association Advisory Board for Chest Diseases	2001-

Chair, Protocol Review Committee CFF Therapeutics Development Network 2002-

GCRC Site Review Committee
NIH-National Center for Research Resources

2002-

JOURNAL MANUSCRIPT REVIEWER

American Journal of Asthma and Allergy for Pediatricians American Journal of Clinical Nutrition American Journal of Respiratory and Critical Care Medicine Annals of Allergy

Chest

Clinical and Diagnostic Laboratory Immunology

Clinical Journal of Sports Medicine

Clinical Immunotherapeutics

Clinical Reviews in Allergy

European Respiratory Journal

Infection and Immunity

International Archives of Allergy and Applied Immunology

Human Gene Therapy

Journal of Adolescent Health

Journal of Allergy, Asthma, and Clinical Immunology

Journal of Clinical Investigation

Journal of Clinical Microbiology

Journal of Infectious Diseases

Journal of Pediatrics

The Lancet

Pediatric Allergy and Asthma

Pediatric Drugs

Pediatric Pulmonology

Pediatric Research

Pediatrics

Respiratory Research

SYMPOSIA, CONFERENCES, AND SESSIONS ORGANIZED

Symposium on Rhinitis: Differentiation and Management in Primary Care Practice, Napa, CA, January 27-28, 1984. Co-sponsored by American Academy of Allergy & Immunology and American Academy of Family Practice. Chair.

GAP Conference on Infection, Immunity and Inflammation in Cystic Fibrosis, Williamsburg, VA, June 6-9, 1988. Sponsored by Cystic Fibrosis Foundation. Co-Chair. Session on Intravenous Immunoglobulin, Protease Inhibitors and Other New Therapies, Fifth Annual North American Cystic Fibrosis Conference, Dallas, TX, October 2-5, 1991. Sponsored by Cystic Fibrosis Foundation. Co-Chair.

Workshop on Clinical Anti-Inflammatory Interventions, Tenth Annual North American Cystic Fibrosis Conference, Orlando, FL, October 24-27, 1996. Co-Chair.

Northern California Cystic Fibrosis Center Physicians and Coordinators Meeting, Napa CA, May 30, 1998. Chair.

Advances in Inhaled Antibiotic Therapy, San Francisco CA, October 9, 1998. Chair.

Lung Disease in Immunoglobulin Deficiency Syndromes. Sunrise Seminar, American Thoracic Society, San Diego CA, April 26, 1999. Co-chair with Valentin Popa.

Consensus Conference on Allergic Bronchopulmonary Aspergillosis. Cystic Fibrosis Foundation, Bethesda MD, June 12-13, 2001. Co-Chair with David Stevens.

Symposium on Non-CF Bronchiectasis and ABPA, North American CF Conference, Orlando FL, October 27, 2001. Co-Chair with Jim Yankaskas.

Symposium on Asthma and ABPA, North American CF Conference, Orlando FL, October 4, 2002. Chair.

Cystic Fibrosis Foundation Williamsburg Conference, Inflammation Session, Williamsburg VA, June 2, 2003. Co-Chair.

Advances Against Aspergillosis International Conference, San Francisco CA, Sept 9-11, 2004. Organizing Committee and Session Chair.

INVITED PRESENTATIONS (selected from 2000-present only)

Children's National Medical Center, Washington DC, January 19, 2000. CF - New Insights and Therapies. Pediatric Grand Rounds.

American College of Chest Physicians/American Academy of Pediatrics, San Diego CA, April 1-4, 2000. A Celebration of Pediatric Pulmonology. Controversies in Sinusitis. The Vulnerable Infant – Bronchopulmonary Dysplasia.

American Thoracic Society/International Lung Conference, Toronto CA, May 6-9, 2000. New Perspectives in Aerosolized Antibiotics. Pediatric Clinical Chest Rounds, Case Discussant.

Johns Hopkins Medical Center. September 7, 2000. Allergic Bronchopulmonary Aspergillosis. Pulmonary Medicine Research Conference.

National Institutes of Health DNA Advisory Committee. September 26, 2000. Phase II Aerosolized Gene Therapy Protocol for Cystic Fibrosis. Public Hearing.

St Louis Cardinal Glennon Children's Hospital/St. Louis University. May 30, 2001. Fungal Complications of Cystic Fibrosis. Grand Rounds. Cytokines in cystic fibrosis. Allergy-Immunology Research Seminar.

Current Concepts in Pediatric Respiratory Disease: San Diego 2001. Children's Hospital San Diego. June 29-30, 2001. Bronchopulmonary Dysplasia: Does it Still Occur and How Should it be Managed?; Cystic Fibrosis: What we've Learned from the Infants and Should we Screen?

South American Congress of Pediatric Pulmonology. Florianopolis Brazil, October 1-5, 2001. Aerosolized Antibiotics.

Community Hospital of Los Gatos Grand Rounds. March 28, 2002. Cystic fibrosis.

Santa Clara Valley Medical Center Pediatric Grand Rounds. May 1, 2002. Cystic Fibrosis.

Respiratory Symposium. Central California Children's Hospital, Madera CA. September 26, 2002. Pathophysiology of Cystic Fibrosis.

North American CF Conference, October 4, 2002. CFF Consensus Conference Recommendations on Diagnosis and Treatment of ABPA.

3rd Anuual Irish Cystic Fibrosis Trust Meeting, Killarney, Ireland, February 8, 2003. Allergic Bronchopulmonary Aspergillosis.

Miami Children's Hospital 38th Annual Pediatric Postgraduate Course, January 27, 2003. Aerosolized Antibiotics in Treatment of Respiratory Infection in Children.

New York Cystic Fibrosis Consortium's Dinner Lecture, March 6, 2003. Treatment Emergent Pathogens: Aspergillus and S. Maltophilia.

UCSF Pulmonary Grand Rounds, San Francisco CA, May 6, 2003. Allergic Bronchopulmonary Aspergillosis.

American Society of Gene Therapy, Workshop on Respiratory Tract: Planning and Executing a Gene Therapy Trial for the Respiratory Tract, Washington DC, June 5, 2003. Aersol Grene Transfer in Cystic Fibrosis: The tgAAVCF Experience.

Postgraduate Institute for Medicine, Update on the Microbiology of Cystic Fibrosis (national teleconference), June 16-18, 2003. Treatment of Emerging Opportunists: Aspergillus.

CFRI Annual Conference, Redwood City CA, July 27, 2003. Gene Therapy Research: How Close are We?

Brazilian Cystic Fibrosis Assocation, Rio de Janeiro, Brazil, September 7-9, 2003. Gene Therapy; Inhalation Antiotics.

Cystic Fibrosis Foundation, North American CF Conference, October 19, 2003. *Plenary Speaker*, Progression of Cystic Fibrosis: Can We Gain the Upper Hand?

Lovelace Respiratory Research Institute, Santa Fe NM, October 14, 2003. New Pharmaceuticals: Inhalational Antibiotics for Airways Infection.

Spanish National Cystic Fibrosis Association, Oviedo, Spain, November 21-22, 2003. Clinical Research in Cystic Fibrosis; Inhalational Antibiotics.

Advances Against Aspergillosis International Conference, San Francisco CA, Sept 9-11, 2004. Session Co-Chair, Immunity and Alergy to Aspergillus. Pathophysiology and Immunology of Allergic Aspergillosis.

SELECTED ABSTRACTS

Lewiston NJ, Moss RB. Prolonged corticosteroid therapy in cystic fibrosis. CF Club Abstr 22:131, 1981.

Moss RB, Hsu YP. IgM and IgG rheumatoid factors in cystic fibrosis compared to rheumatic diseases of childhood and controls. Clin Res 30:96A, 1982.

Moss RB, Hsu YP. Autoimmunity in cystic fibrosis: evidence against polyclonal B cell activation. *J Allergy Clin Immunol* 69:S112, 1982.

Lewiston NJ, Moss RB. Circulating immune complexes decrease during corticosteroid therapy in cystic fibrosis. *Pediatr Res* 16:345A, 1982.

Moss RB, Hsu YP, Leahy M, Halpern G. IgG₄ antibodies to Pseudomonas aeruginosa in cystic fibrosis. *CF Club Abstr* 23:13, 1982.

Leong RE, Moss RB, Blessing J, Cheung NKV, Cheung I, Lewiston NJ. IgE and IgG antibodies to case in in suspected cow's milk allergy. *Ann Allergy* 50:352, 1983.

Moss RB, Hsu YP. Humoral immune response to inhaled and parenteral allergens: role of IgG₄ antibody in clinical protection. *J Allergy Clin Immunol* 73:138, 1984.

Moss RB, Hsu YP, Kwasnicki M, Reid MJ. A quantitative immunoenzymatic assay for allergen-specific IgE antibodies. Comparison with three other in vitro assays. *Clin Res* 32:41A, 1984.

Kwasnicki JM, Moss RB, Cheung NKV, Reid MJ. Towards a quantitative enzyme-linked immunosorbent assay for specific IgE. *J Allergy Clin Immunol* 73:152, 1984.

Blessing J, Leong RE, Machtinger S, Lewiston N, Moss RB. Once a day theophylline in asthmatic adolescents. *Clin Res* 32:61A, 1984.

Blessing J, Leong RE, Machtinger S, Lewiston N, Moss RB, Rubinstein S, Hindi R. Once daily theophylline (Uniphyl) for treatment of bronchospasm in patients with cystic fibrosis and asthma. *Ann Allergy* 52:235, 1984.

Moss RB, Hsu YP. A quantitative immunoenzymatic assay for grass pollen-specific IgG antibodies. J Allergy Clin Immunol 75:175, 1985.

Somma C, Silverman E, Moss RB. Normal suppressor T cell function in hospitalized patients with cystic fibrosis. Clin Res 33:82A, 1985.

Hindi R, Hsu YP, Moss RB, Lewiston NJ. In vitro screening for allergic antibodies in young children. *Ann Allergy* 54:360, 1985.

Moss RB, Hsu YP. Alveolar macrophage phagocytosis of Pseudomonas aeruginosa opsonized by normal, cystic fibrosis, and murine monoclonal antibodies. *Am Rev Respir Dis* 131:A22, 1985.

Moss RB, Hsu YP, Larrick JW. Opsonization of Pseudomonas aeruginosa by human polyclonal, murine monoclonal, and cystic fibrosis-derived human monoclonal antibodies. *CF Club Abstr* 26:23, 1985.

Adams L, Moss RB, Hindi R, Rubinstein S, Sullivan M, Lewiston N. Effect of nocturnal feeding via percutaneous endoscopic gastrostomy on nutrition and growth in cystic fibrosis. *CF Club Abstr* 26:83, 1985.

Larrick JW, Moss RB, Hart S, Hsu YP, Dyer B. Production of type-specific human monoclonal antibodies to Pseudomonas aeruginosa. *CF Club Abstr* 26:133, 1985.

Moss RB, Hsu YP, Lewiston NJ, De Lange G. Allotype, isotype, and immune response in cystic fibrosis. *J Allergy Clin Immunol* 79:143, 1987.

Moss RB, Hsu YP, Reid MJ. Dissecting the atopic immune response to grass pollen. J Allergy Clin Immunol 79:215, 1987.

Moss RB, Hsu YP, Lewiston NJ, De Lange G. Impaired natural IgG₂ antibody response to polysaccharide antigens and decreased Km(1)-A2m(2) allotypes in cystic fibrosis. *Pediatr Res* 21:330A, 1987.

Moss RB, Eichler I. Defective antibody-mediated opsonization of Pseudomonas aeruginosa in cystic fibrosis: an isotype-dependent defect? *J Allergy Clin Immunol* 81:298, 1988.

Moss RB, Kurland G, Ayin S, Lewiston NJ, Cheung ATW. A primate model of chronic Pseudomonas bronchopneumonia. Am Rev Respir Dis 137:318, 1988.

Moss R, Joris L, Hsu Y, Eichler I. Role of antigen and isotype in defective opsonization of Pseudomonas aeruginosa in CF. *Pediatr Pulmonol* S2:124, 1988.

Moss RB, Joris L, Hsu YP, Van Wye J, Eichler I. Are IgG₄ antibodies to lipopolysaccharide antigens of Pseudomonas aeruginosa opsonophagocytic blocking factors in cystic fibrosis? *American Association for the Advancement of Science, Annual Meeting Abstracts*, p. 59, 1989.

Moss RB, Joris L, Eichler I, Van Wye J, Hsu YP. Pseudomonas aeruginosa endobronchial infection in cystic fibrosis induces nonopsonic IgG₂ and IgG₄ lipopolysaccharide-specific antibodies. *Pediatr Res* 25:185A, 1989.

Cheung ATW, Moss RB, Lewiston NJ, Leong A, Novick WJ. Chronic Pseudomonas endobronchitis and pentoxifylline efficacy study. *Am Rev Respir Dis* 141:A87, 1990.

Hsu YP, Moss RB. Performance of a microtiter plate histamine release assay employing a monoclonal antibody. *J Allergy Clin Immunol* 87:280, 1991.

Bocian RB, Hsu YP, Van Schooten W, Gardner P, Nghiem P, Moss RB. Antigen-specific T cell clones from cystic fibrosis patients. *Pediatr Pulmonol* Suppl 6:304, 1991.

Moss RB, Loutit CL, Davidson J, Hsu YP. Mechanism of β-lactam induced mediator release in CF. *Pediatr Pulmonol* Suppl 6:306, 1991.

Bocian R, Hsu YP, Kemna M, Dong A, Gardner P, Moss R. Phenotypic characterization of T cell clones derived from patients with cystic fibrosis. *Pediatr Pulmonol* Suppl 8: 318, 1992.

Kemna M, Hsu YP, Bocian R, Moss R. Expression of CFTR in T cells: demonstration by flow cytometry and catalytic immunoprecipitation. *Pediatr Pulmonol* Suppl 8: 318, 1992.

Bocian RC, Hsu Y-P, Kemna M, Dong Y, Gardner P, Moss RB. Cystic fibrosis transmembrane conductance regulator expression in T cell clones from cystic fibrosis patients. *Am Rev Respir Dis* 147: A26 and A718, 1993.

Lim JJ, Moss RB, Palmer J, Harkins EA, Marcus R, Bachrach LK. Bone mineral status in cystic fibrosis: risk factors for osteoporosis. *Pediatr Pulmonol* Suppl 9:278, 1993.

Moss R, Desch J, King V, Toy KJ, Sinicropi D, Shak S. Biochemical and biophysical characterization of sinus secretions in CF. *Pediatr Pulmonol* Suppl 9:266, 1993.

Bocian RC, Hsu Y-P, Kemna M, Olds L, Dong Y, Gardner P, Moss RB. Direct demonstration of CFTR protein expression and Cl⁻ channel dysregulation in cystic fibrosis T cells. *Pediatr Pulmonol* Suppl 9:204, 1993.

Moss R, Bocian R, Hsu Y-P, Yssel H. Is CF a T_H2 immunoinflammatory disease? *Pediatr Pulmonol* Suppl 9:289, 1993.

Hamilton JR, Noble A, Moss RB, Bocian RC. Synergy testing in antibiotic selection for cystic fibrosis patients with multi-resistant Pseudomonas. *Pediatr Pulmonol* Suppl 9:262, 1993.

Sinicropi D, Prince W, Lofgren JA, Baker D, Moss R, Smith AL, Shak S. Measurement of DNA concentration and length in cystic fibrosis sputum. *Pediatr Pulmonol* Suppl 10:238, 1994.

Gonzalez A, Troup N, Mickelsen P, Moss R. Pseudomonas aeruginosa in sinuses and airways of CF patients: genomic fingerprinting by pulsed field gel electrophoresis. *Pediatr Pulmonol* Suppl 10:252-253, 1994.

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